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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/696,982 10/27/00 BRINGHURST

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HM12/1102  
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 EXAMINER

ULM, J

 ART UNIT PAPER NUMBER

1646

DATE MAILED:

11/02/01

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. <b>09/696,982</b>	Applicant(s) <b>Bringhurst et al.</b>
Examiner <b>John Ulm</b>	Art Unit <b>1646</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 2 and 6-8 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 2 and 6-8 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3      20)  Other: \_\_\_\_\_

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1) Claims 2 and 6 to 8 are pending in the instant application. Claims 2, 7 and 8 have been amended and claims 1 and 3 to 5 have been canceled as requested by Applicant in Paper Number 2, filed 27 October of 2001.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and **to prevent possible harassment by multiple assignees**. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2) Claims 2 and 6 to 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,183,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matter is the patent is encompassed in its entirety by the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3) Claims 2 and 6 to 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is vague and indefinite because there is no clear antecedent basis for “the adenylyl cyclase or phospholipase C pathways”. What “adenylyl cyclase or phospholipase C pathways” is the claim referring to? Claims 6 to 8 are vague and indefinite in so far as they depend from claim 2 for this element.

4) Claims 2 and 6 to 8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Simply measuring the effects of a compound on the adenylyl cyclase or phospholipase C pathway of a cell expressing a heterologous receptor provides no information on the action of that compound on the heterologous receptor. There are numerous mechanisms through which a compound could effect either of these two pathways without interacting with a heterologous receptor. Clearly some additional step or steps are required to permit an artisan to distinguish between a compound which effects either of these two pathways directly or through a mechanism other than a heterologous receptor and a compound which effects either of these pathways indirectly by activating or inhibiting the heterologous receptor of interest.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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5) Claims 2 and 6 to 8 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Because the claimed invention is incomplete for those reasons given under 35 U.S.C. 112, second paragraph, above, it is inoperative.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6) Claims 2 and 6 to 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Catanzariti et al. publication (BioTechniques 15(3):474-479, Sep. 1993) in view of the combination of the Segre et al. patent (5,494,806) and the Bringhurst et al. publication (Endocrinology 132(5):2090-2098, May 1993). The Catanzariti et al. publication described a method of “rapidly” identifying LLC-PK1-derived cell lines expressing heterologous receptors that couple to G<sub>s</sub>-proteins by transfecting LLC-PK1 cells with DNA encoding a heterologous G

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protein-coupled receptor and screening for ligand-induced, cyclic AMP-mediated urokinase activity. This publication concluded with the statement that "we conclude that LLC-PK<sub>1</sub> cells represent an attractive system for the expression of any G<sub>s</sub>-coupled receptor since agonist-inducible uPA activity allows the rapid identification and characterization of cell lines that functionally express such receptors". The method of Catanzariti et al. differs from the instant claims because Catanzariti et al. utilized LLC-PK1 cells stably transfected with a recombinant DNA encoding a murine β<sub>2</sub> adrenergic receptor whereas the instant claims encompass a method which utilizes LLC-PK1 cells stably transfected with a recombinant DNA encoding a human parathyroid hormone/parathyroid hormone related peptide receptor (PTHR).

Figures 6A to 6G of the Segre et al. patent described an isolated DNA encoding a human parathyroid hormone receptor. The text on line 61 in column 19 of this patent expressly identified the LLC-PK1 cell line as one of five preferred cell lines for the recombinant expression of the PTH/PTHrP receptor described therein. The Bringhurst et al. publication disclosed the production of LLC-PK1 cells which were stably transfected with DNA encoding the rat and opossum PTHRs that were described in the Segre et al. patent. Bringhurst et al. further disclosed that those receptors coupled to the G<sub>s</sub>-proteins in those cells as demonstrated by ligand-stimulated adenylate cyclase activity. Because an artisan of ordinary skill in the art of molecular biology was well aware that the ultimate value of the information obtained from an assay like that which was described by Catanzariti et al. would lie in the applicability of that information to human subjects that artisan would have found it *prima facie* obvious to have

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transfected the DNA encoding the human PTH/PTHrP receptor of Segre et al. into the LLC-PK1 cells of Catanzariti et al. to permit the pharmacological characterization of that receptor. Because the Bringhurst et al. publication had shown that LLC-PK1 cells could be stably transformed with a DNA encoding a mammalian PTH/PTHrP receptor and that this receptor couples to the adenylate cyclase system of those cells, an artisan had more than a reasonable expectation that a DNA encoding the human PTH/PTHrP receptor of Segre et al. could be functionally and stably expressed in the LLC-PK1 cells of Catanzariti et al. and their activity assayed by measuring urokinase-type plasminogen activator as taught therein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800